K032658

SEP 11 2003

Exhibit #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

   Microlife Intellectual Property
   Max Schmidheiny-Strasse 201
   9435 Heerbrugg / Switzerland

   Date Prepared: August 15, 2003

   Contact: Mr. Gerhard Frick

2. **Name of the Device:**

   Microlife Digital Underarm Electronic Thermometer, Model MT18E1-1 (V932-1)

3. **Predicate Device Information:**

   Micro Idea Instrument Digital Thermometer, Model MT 3001/5001, K#851146, Microlife Corporation

4. **Device Description:**

   Unlike regular thermometers, the unique elbow of the Digital Underarm thermometer is designed to find the " hotspot" easily and comfortably every time.

   The basic principle of this thermometer is that change of thermistor resistance, caused by changes of temperature, are converted to changes of frequency of R-C oscillator circuit, Therefore, temperature can be given by measuring the frequency of oscillator.

5. **Intended Use:**

   The Microlife Digital Underarm Thermometer MT 18E1-1 (V932-1) is designed specifically for measuring underarm (axillary) temperatures.

6. **Comparison to Predicate Devices:**

The Microlife Intellectual Property' s digital underarm thermometer, Model MT18E1-1 (V932-1) is substantially equivalent to the Micro Idea Instrument Digital Thermometer, (Model MT3001/5001) K#851146.

The new model MT18E1-1 (V932-1) has the same intended use for human body
temperature measurement but focuses especially on underarm temperature and is similar in design to the 510(k) cleared device except for the unique elbow sensor design.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1112, as well as IEC60601-1 and IEC60601-1-2 requirements and well as ISO 10993 biocompatibility testing.

Guidance documents included the "FDA Guidance on the Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers".

8. **Discussion of Clinical Tests Performed:**

Not applicable.

9. **Conclusions:**

The Microlife Digital Underarm Thermometer has the same intended use and similar technological characteristics as the Micro Idea Instrument Digital Thermometer, (Model MT3001/5001). Moreover, bench testing contained in this submission supplied demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Digital Underarm Thermometer is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2003

Microlife Intellectual Property GMBH
C/O Mr. Robert Mosenkis
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K032658
Trade/Device Name: Microlife Model MT18E1-1 (V932-1) Digital Underarm Electronic Thermometer
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: August 27, 2003
Received: August 28, 2003

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): _____

Device Name

Indications For Use:

Microlife Digital Underarm Thermometer MT18E1-1 (V932-1) is designed specifically for measuring underarm (axillary) temperatures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The Counter Use** ✓
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Fabiola Cecconi

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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